Hepatitis B and C Testing: Quality Assurance (QA) Manual

Virginia Department of Health,
Office of Epidemiology,
Division of Disease Prevention

VDH VIRGINIA DEPARTMENT OF HEALTH

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Revision History

This document and its revisions are maintained at the following link:
http://www.vdh.virginia.gov/epidemiology/DiseasePrevention/Programs/ViralHepatitis/

Section	Title	Revision Date
All	Hepatitis B and C Testing Guidelines - Draft	9/7/2016
All	Full document revision	6/1/2017
	Contact Information Update	3/12/2018

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Goals of the Viral Hepatitis Testing Program

- Increase the number of individuals who are aware of his or her HBV/HCV status.
- Minimize the public health burden of infection with hepatitis B (HBV) and hepatitis C virus (HCV).
- Provide counseling in order to decrease behaviors associated with transmission of HBV/HCV.
- Link clients with positive HBV or HCV serology to care services.

Intended Use

This document is intended to serve as a guide for viral hepatitis testing in local health departments (LHDs) that are funded through the Virginia Department of Health's (VDH) Office of Epidemiology (OEpi). This guide aims to help in the identification of those who would benefit from a test for HBV or HCV, interpretation of test results, and subsequent steps for individuals with diagnosed infection.

Contact Information

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Relevant State Laws

HBV and HCV are reportable by state law (Sections 32.1-36 and 32.1-37 of the *Code of Virginia* and 12 VAC 5-90-80 and 12 VAC 5-90-90 of the Board of Health *Regulations for Diseases Reporting and Control* - http://www.vdh.virginia.gov/surveillance-and-investigation/commonwealth-of-virginiastate-board-of-health/).

Informed Consent

For a counselor to administer the test to a client, the client must first give consent. The following should be completed to ensure informed consent: (1) Discuss the testing options available at the test site (rapid and/or conventional testing), the difference between a screening and confirmatory test, and the follow-up procedures for both a negative and a reactive result. (2) Ask client if they have any questions or concerns about the test. (3) Each site will follow their own procedure for obtaining a client's signature on the consent form they have in place. (4) To release test results to anyone other than the client or VDH, the client must sign an authorization to release information.

OSHA Requirements

All sites that collect blood samples for traditional and/or rapid testing must meet the OSHA standards for blood-borne pathogens. Information regarding OSHA standards can be found at: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS.

Hepatitis B Virus Testing Guidelines

Determining Eligibility for Hepatitis B Virus Testing

VDH funds HBV testing for uninsured and non-chargeable clients, over 9 months old, meeting at least one of the following criteria:

One-time testing
People from geographic regions with a HBsAg prevalence of greater than or equal to 2%[2] (see Appendix G)
U.S. born person not vaccinated as infants, whose parent(s) were born in geographic regions with HBsAg prevalence of greater than or equal to 8% (see Appendix G)
Children born to a HBV infected mother
Clients who could benefit from a HBV test
Persons who have HIV infection
Persons with selected medical conditions who require immunosuppressive therapy
Persons with liver disease of unknown etiology (elevated ALT/AST)
Persons who are household contacts and/or sexual partners of HBV infected people
Persons who inject drugs (PWID/IDU) or have ever injected drugs
Men who have sex with men (MSM)
Persons who have been or are currently incarcerated
Persons who engage in transactional sex work for money or drugs
Persons who are the source of blood or body fluid exposures (e.g. needle stick injury)

Collection of the Blood Specimen

All blood draws must be performed at the health department. VDH funding does not support additional cost for blood draws or administrative expenses; therefore, if clients are referred to LabCorp, the cost of the blood draw must be paid with local funds.

Blood specimen collection supplies and requirements for serum (HBV combo test):

- Collection media: 10 mL red-top tube or gel-barrier tube
- Volume: 7 mL of serum is the *minimum* amount required to run the HBV combo test
- Specimen storage instructions: room temperature
- Sample stability: 14 days at room temperature, refrigerated or frozen and 3 freeze/thaw cycles

Completion of the LabCorp OEpi Requisition Form

Use the OEpi LabCorp requisition form to request a **HBV combo test (HBsAb+HBcAb+HBsAg) with reflex to IgM** test (LabCorp test number 0219949) for patients who meet at least one defined criteria and are uninsured or non-chargeable. Other hepatitis B tests are not authorized on the account.

Interpretation of Results

Refer to Appendix A to interpret the test results.

Follow up and Reporting Procedures

- If the results necessitate a referral to care, provide the client with a local referral within the client's geographic area for follow up care, and a copy of his/her test results.
- If determined to have HBV infection (HBsAg and anti-HBc (HBcAb) are positive) interpret and report anti-HBc IgM results as follows:
- **Anti-HBc IgM results:**
    - Positive results, report as acute
    - Negative results, report as chronic
- Refer to 12 VAC 5-90-80 and 12 VAC 5-90-90 for reporting regulations.

Hepatitis C Virus Testing Guidelines

Determining Eligibility for Hepatitis C Virus Testing

In accordance with CDC, USPSTF and WHO testing recommendations, VDH funds HCV testing for uninsured and non-chargeable clients who meet at least one of the following criteria:

One-time testing
Persons born from 1945 – 1965
Clients who could benefit from a HCV test
Persons who inject drugs (PWID or IDU) or have ever injected drugs
Persons who have HIV infection
Persons with liver disease of unknown etiology (i.e. elevated ALT/AST)
Persons engaging in intranasal cocaine use and other non-injecting illegal drug use
Men who have sex with men (MSM)
Persons who engage in transactional sex work for money or drugs
Persons who were ever on long-term hemodialysis
Persons who received a transfusion or an organ transplant before July 1992, or clotting factor concentrates produced before 1987
Persons with a history of tattooing or body piercing if the procedure was done where infection control practices are substandard
Persons with a long-term steady sexual partner who is HCV-positive
Persons who have been or are currently incarcerated
Testing based on recognized exposure
Healthcare, emergency medical and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood
Children born to a HCV-infected mother (to avoid detecting maternal antibody, these children should not be tested before age 18 months)
Testing based on rapid test result
Persons with a reactive rapid HCV antibody test result from a VDH-affiliated testing site (e.g. Walgreens Pharmacy, community-based organization)

Collection of the Blood Specimen

All blood draws must be performed at the health department. VDH funding does not support additional cost for blood draws or administrative expenses; therefore, if clients are referred to LabCorp, the cost of the blood draw must be paid with local funds.

Blood specimen collection supplies and requirements for HCV conventional blood draw testing:

- Container: Red-top tube or gel-barrier tube
- Collection: If tube other than a gel-barrier tube is used, transfer separated serum to a plastic transport tube. Do not freeze gel-barrier tube (pour off serum first)
- Volume: 3mL of serum is the required *minimum* to run the test; 5mL is preferred
- Specimen storage instructions: Refrigerate
- Stability Requirements: 3 days room temperature; 14 days refrigerated and frozen; 3 freeze/thaw cycles

Completion of the LabCorp OEpi Requisition Form

Use the OEpi LabCorp requisition form to request a **HCV Antibody reflex to NAA** (LabCorp test number 144045) for patients who meet the defined criteria and are uninsured or non-chargeable (e.g., reactive rapid HCV antibody test from a VDH-affiliated testing site). The "reflex to NAA" indicates that if the HCV Ab is positive, LabCorp will automatically test for HCV RNA via nucleic acid amplification (NAA). HCV RNA is the confirmatory test. Other hepatitis C tests are not authorized on the account. If an alternative test is clinically indicated, contact the viral hepatitis testing coordinator for assistance.

Interpretation of Results

Refer to Appendix C for a guide to interpretation of the HCV test results.

Follow up and Reporting Procedures

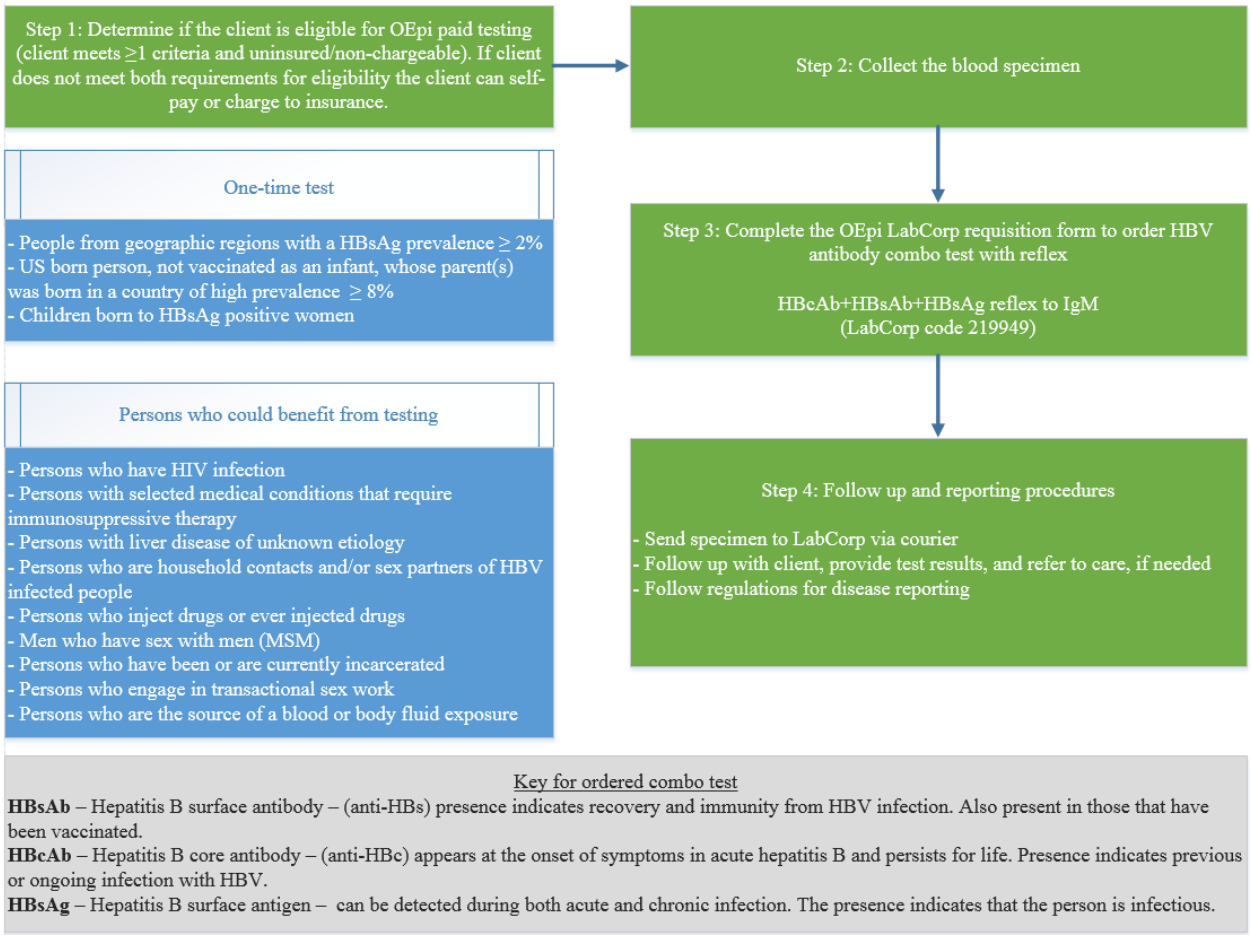
- If the results necessitate a referral to care, provide the client with a local referral within the client's geographic area for follow up care, and a copy of his/her test results.
- Refer to 12 VAC 5-90-80 and 12 VAC 5-90-90 for reporting regulations.

Appendix A: HBV Results Interpretation

Interpretation of HBV Serologic Results		
Interpretation (recommended action)	**Test Name***	**Result**
Susceptible/Never infected **(recommend vaccination)**	HBsAg	–
	anti-HBc	–
	anti-HBs	–
Early acute **(refer to care)** OR Receipt of vaccine w/ in several weeks	HBsAg	+
	anti-HBc	–
	IgM anti-HBc	–
	anti-HBs	–
Acute infection **(refer to care)**	HBsAg	+ †
	anti-HBc	+
	IgM anti-HBc	+
	anti-HBs	–
Past infection with recovery, immunity to new infection	HBsAg	–
	anti-HBc	+
	anti-HBs	+
Chronic infection **(refer to care)**	HBsAg	+
	anti-HBc	+
	IgM anti-HBc	–
	anti-HBs	–
Four possible interpretations **(refer to care)**: - False positive HBc Ab/susceptible - Past infection/resolved - "Low level" chronic infection, unlikely to be infectious, except in certain circumstances (e.g. infected mother gives birth) - Resolving acute infection	HBs Ag	–
	anti-HBc	+
	IgM anti-HBc	–
	anti-HBs	–
Vaccinated	HBs Ag	–
	anti-HBc	–
	anti-HBs	+

*Test names may also appear as the following: Hepatitis B surface antigen (HBsAg); antibody to hepatitis B surface antigen (HBsAb or anti-HBs); antibody to hepatitis B core antigen (HBcAb or anti-HBc); IgM antibody to hepatitis B core antigen (IgM anti-HBc).
†HBsAg starts positive, as the acute infection resolves it becomes negative.

Appendix B: HBV Testing Process Flow



Key for ordered combo test

HBsAb – Hepatitis B surface antibody – (anti-HBs) presence indicates recovery and immunity from HBV infection. Also present in those that have been vaccinated.

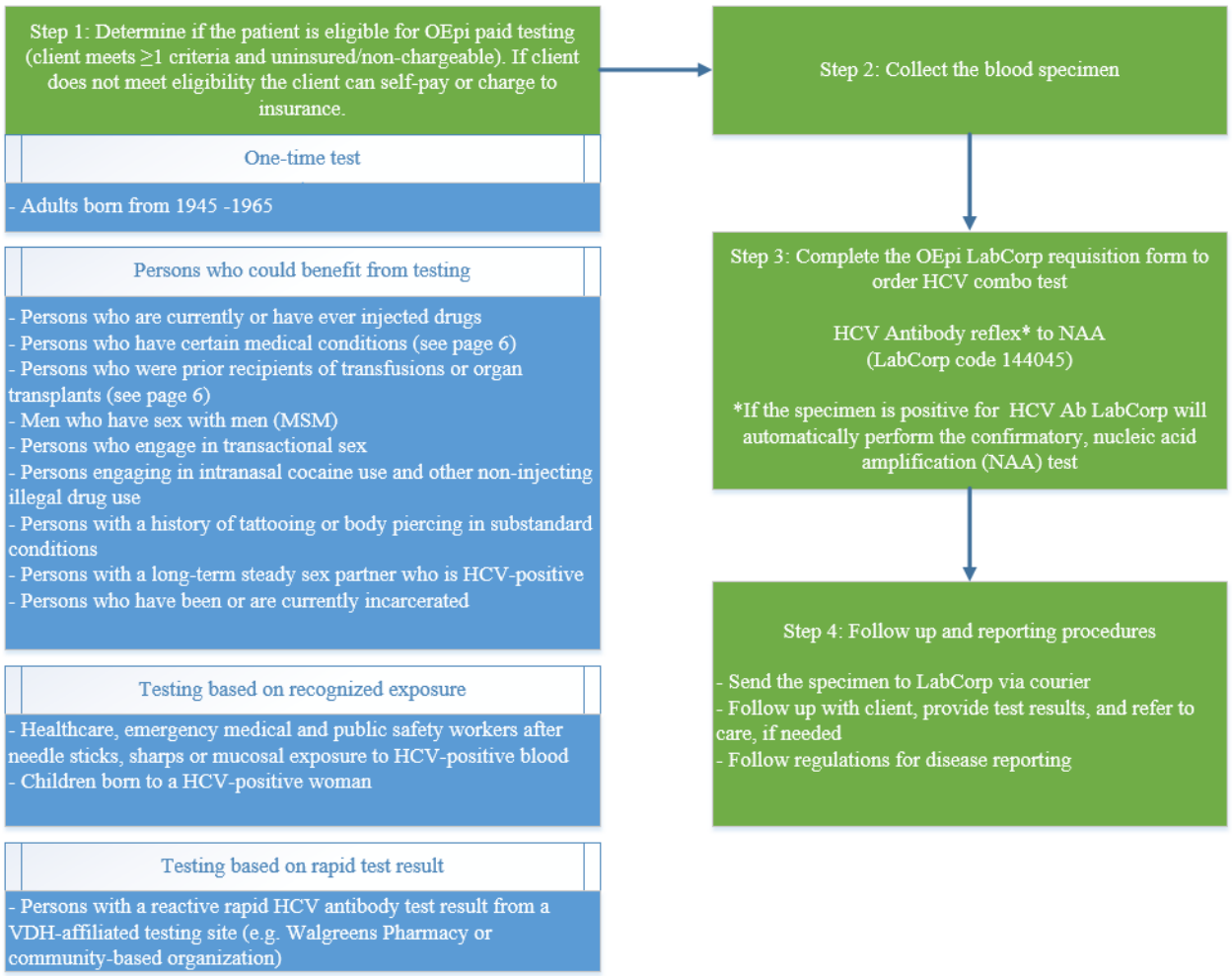
HBcAb – Hepatitis B core antibody – (anti-HBc) appears at the onset of symptoms in acute hepatitis B and persists for life. Presence indicates previous or ongoing infection with HBV.

HBsAg – Hepatitis B surface antigen – can be detected during both acute and chronic infection. The presence indicates that the person is infectious.

Appendix C: HCV Results Interpretation

Interpretation of HCV Serologic Results			
Interpretation	**Test Name***	**Result**	**Additional Information**
Never infected/Susceptible	Anti-HCV	–	The patient is not infected
Three interpretations: - Current infection - Past/Resolved infection - False-positive	Anti-HCV	+†	A positive anti-HCV must be followed by an HCV RNA test to determine which of the possible interpretations is correct
Two interpretations: - Past/Resolved infection - False-positive antibody test	HCV RNA	–	Consider testing with another HCV antibody assay to differentiate past, resolved infection from biologic false positivity for HCV antibody. If a known exposure occurred within the prior 6 months, repeat testing may be necessary.
Current HCV infection	HCV RNA	+	**Refer to care**
* The anti-HCV test may also be referred to as the HCV Ab test. †10-11 weeks after exposure 40% of infected persons will be positive (+); at 15 weeks post-exposure ~80% will be anti-HCV positive (+); and at 6 months post-exposure almost all will be anti-HCV positive (+). After infection, anti-HCV generally remains positive for life.			

Appendix D: HCV Testing Process Flow



Appendix E: WebVision and LabCorp Procedure Codes

WebVision and LabCorp Procedure Codes

	WebVision Procedure Code	LabCorp Test Code	Description
Hepatitis B	L219949	219949	HBsAb + HBcAb + HBsAg reflex to IgM
Hepatitis C	L144045	144045	HCV Antibody reflex to NAA

Appendix F: Quick Reference Guide to Determining Eligibility for Hepatitis Testing

Conventional Hepatitis B (HBV) and Hepatitis C (HCV) Testing in Local Health Departments

Clients who could benefit from a HBV and/or HCV test:	**HBV**	**HCV**
Persons from geographic regions with a HBsAg prevalence of greater than or equal to 2%*	X	
U.S. born persons not vaccinated as infants, whose parent(s) were born in geographic regions with HBsAg prevalence of greater than or equal to 8%*	X	
Persons who are household contacts and/or sexual partners of HBV infected people	X	
Persons with selected medical conditions who require immunosuppressive therapy	X	
Persons who are the source of blood or body fluid exposures that might warrant post-exposure prophylaxis (e.g., needle stick injury)	X	
Persons who have HIV infection	X	X
Persons with liver disease of unknown etiology (i.e. elevated ALT/AST)	X	X
Persons who inject drugs (PWID or IDU) or have ever injected drugs	X	X
Men who have sex with men (MSM)	X	X
Persons who have been or are currently incarcerated	X	X
Persons who engage in transactional sex work for money or drugs	X	X
Children born to a HBV or HCV infected mother (testing respective of mother's infection)	X	X
Persons engaging in intranasal cocaine use and other non-injecting illegal drug use		X
Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood		X
Persons who were ever on long-term hemodialysis		X
Persons born from 1945-1965		X
Persons who received a transfusion or an organ transplant before July 1992, or clotting factor concentrates produced before 1987		X
Persons with a history of tattooing or body piercing if the procedure was done where infection control practices are substandard		X
Persons with a long-term steady sexual partner who is HCV-positive		X
Persons with a reactive rapid HCV antibody test result from a VDH-affiliated testing site (e.g., Walgreens Pharmacy, community-based organization)		X

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*See reverse side for a list of countries/populations

Additional information about testing procedures, risk criteria source citations, and test interpretation is located in the Viral Hepatitis Testing Quality Assurance Manual, available at http://www.vdh.virginia.gov/disease-prevention/disease-prevention/viral-hepatitis/providers/.

Appendix G: Global HBsAg Prevalence

HBsAg Prevalence ≥ 2%

Region	Countries/populations
Africa	All
Asia	All
Australia & South Pacific	All except Australia and New Zealand
Middle East	All except Cyprus and Israel
Eastern Europe	All except Hungary
Western Europe	Malta, Spain, and indigenous populations in Greenland
North America	Alaska natives and indigenous populations in northern Canada
Central America	Guatemala and Honduras
South America	Ecuador; Guyana; Suriname; Venezuela; and Amazonian areas of Bolivia, Brazil, Colombia, and Peru
Caribbean	Antigua and Barbuda, Dominica, Grenada, Haiti, Jamaica, St. Kitts and Nevis, St. Lucia, and Turks and Caicos Islands

HBsAg Prevalence ≥ 8%

Region	Countries/populations
Africa	Angola, Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Gambia, Ghana, Guinea, Liberia, Malawi, Mali, Mauritania, Mozambique, Namibia, Niger, Nigeria, Senegal, Sierra Leone, Somalia, South Sudan, Sudan, Swaziland, Togo, Uganda, Zimbabwe
Asia	Laos, Mongolia, Vietnam
Australia & South Pacific	Kiribati, Nauru, Niue, Papua New Guinea, Solomon Islands, Tonga, Vanuatu
Middle East	Djibouti, Yemen
Eastern Europe	Kyrgyzstan
Western Europe	None
North America	None
Central America	None
South America	None
Caribbean	Haiti

References

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2) Centers for Disease Control and Prevention. (2015 October 5). *Testing and Public Health Management of Persons with Chronic Hepatitis B Virus Infection*. Retrieved from Viral Hepatitis : https://www.cdc.gov/hepatitis/hbv/testingchronic.htm

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4) Centers for Disease Control and Prevention . (2017 January 27). *Hepatitis C FAQs for Health Professionals*. Retrieved from Viral Hepatitis : https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#c1

5) U.S. Preventative Services Task Force. (2016 December). *Final Recommendation Statement, Hepatitis C: Screening*. Retrieved from Recommendations for Primary Care Practice: https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/hepatitis-c-screening

6) World Health Organization. (2016). *Guidelines for the Screening, Care, and Treatment of Persons with Chronic Hepatitis C Infection.* Geneva: World Health Organization.

7) Centers for Disease Control and Prevention. (2017 June 13). *Travelers' Health.* Retrieved from Infectious Diseases Related to Travel - Hepatitis B: https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/hepatitis-b